Medical Science

25(118), December, 2021

Adverse effects of Pfizer-BioNTech vaccine among adolescents aged 12-18 in Saudi Arabia

To Cite:
Marglani OAR, Qashqari MB, Alnashri MT, Alharbi HA, Namenkani MI, Alnashri NT, Alamri MS, Alzahrani KT. Adverse effects of Pfizer-BioNTech vaccine among adolescents aged 12-18 in Saudi Arabia. Medical Science, 2021, 25(118), 3421-3430

Author Affiliation:
[1]Consultant, Rhinologist, ORL, HNS surgeon Professor, Faculty of Medicine - Otolaryngology, head and neck department, Umm Al-Qura University, Makkah, Saudi Arabia
[2]Medical student, University of Jeddah, Jeddah, Saudi Arabia
[3]MBBS, Saudi board of Internal Medicine Resident, King Abdullah Medical Complex, Jeddah, Saudi Arabia
[4]BDS, PGD in Endo, Ministry of Health, Kingdom of Saudi Arabia

✉Corresponding author:
Osama Abdul Rahman Marglani
Consultant, Rhinologist, ORL, HNS surgeon Professor, Faculty of Medicine - Otolaryngology, head and neck department, Umm Al-Qura University, Makkah, Saudi Arabia
Email: omarglani@imc.med.sa

Peer-Review History
Received: 14 November 2021
Reviewed & Revised: 15/November/2021 to 13/December/2021
Accepted: 14 December 2021
Published: December 2021

Peer-review Method
External peer-review was done through double-blind method.

Osama Abdul Rahman Marglani[1]✉, Mohammed Bakr Qashqari[2], Meshal Talal Alnashri[2], Hassan Abdulmohsen Alharbi[2], Mohammed Ibrahim Namenkani[2], Nora Talal Alnashri[3], Mohammed Saad Alamri[3], Khames Torki Alzahrani[4]

ABSTRACT

Background: Since its discovery in China in 2019, the Coronavirus illness (COVID-19) has posed a worldwide threat. The severe acute respiratory syndrome coronavirus 2 is to blame (SARS-CoV-2). SARS-CoV-2 is a highly contagious and transmissible virus that endangers human life and health. Several COVID-19 vaccinations have been linked to serious side effects. To examine the adverse effects of the Pfizer-BioNTech vaccine among adolescents aged 12-18 in Saudi Arabia. *Methods:* Between August 2020 and September 2021, we conducted a cross-sectional online survey among Saudi Arabian adolescents aged 12 to 18. An online questionnaire was employed to collect data. The social sciences statistical program was used to analyze the data (SPSS, version 27.0). *Results:* The research analyzed 1,599 responses from the online questionnaires. The study participants comprised 45.3% males and 54.7% females. The most common symptoms that were associated with the first dose among the study participants included pain (39.9%), swelling (17.5%), redness (14.1%), warmth (13.8%), fever (16.3%), chills (9.2%), muscle pain (18.5%), joint pain (9.6%), headache (19.0%), and dizziness (10.7%). Comparison to find associations with symptoms were done with gender and previous diagnosis of COVID-19, the results revealed several significant associations with various symptoms reported by the participants (P-value<0.05). *Conclusion:* The adverse effects of the Pfizer-BioNTech vaccine observed among adolescents in Saudi Arabia included swelling, redness, warmth, fever, chills, muscle pain, joint pain, headache, and dizziness. This study recommends a follow-up on patients with negative side effects to determine the severity of the symptoms and hospitalization rate.

Keywords: Pfizer-BioNTech vaccine, COVID-19, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

1. INTRODUCTION

Since 2002, three significant diseases have been recorded, including SARS-CoV, MERS-CoV, and the most current COVID-19 virus that also can be called SARS-CoV-2. The virus has caused three major epidemics of coronavirus in 2002, 2012, and 2019. The last one has quickly spread from Wuhan, China, in mid-December 2019 to a large world area that includes more than 197 countries (Alhazmi et al., 2021). Coronaviruses, which are members of the Coronaviridae family, are considered causative agents for respiratory infections in mammals, including bats, camels, masked palm civets, and birds. Coronavirus infection symptoms and tissue tropism can vary from host to host. In coronavirus infection, humans can have asymptomatic course of disease or fever, cough, shortness of breath, and gastrointestinal discomfort. In certain circumstances, coronavirus infections can lead to severe pneumonia and, eventually, death, particularly in old and immunocompromised individuals (Almaghaslah et al., 2021). To face a highly contagious disease, we need effective solutions, like vaccines that can help us control and prevent the spread of infectious diseases. Since the middle of the 20th century, several infectious illnesses and their aftermath have been successfully eradicated using vaccines (Elsaid et al., 2020).

The COVID-19 pandemic had to accelerate the steps in the typically long vaccine development process as it was considered an emergency. Many rapid genetic platforms help uscreate vaccines quickly (Bahrani et al., 2020). Gene-based vaccinations (including mRNA and DNA vaccines) include genetic guidance for the cells of the vaccine recipient to produce antigen. BioNTech and Pfizer developed "BNT162b2 (Comirnaty®)," which is a nucleoside-modified mRNA vaccine that has been designed to prevent the spread of coronavirus disease 2019 (COVID-19), which is the causative agent of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Bahrani et al., 2020). BNT162b2 was generated via BioN-Tech's Lightspeed Project, which led to the clinical development of mRNA vaccine candidates in less than three months (Bahrani et al., 2020).

In April 2020, Phase I/II clinical studies were started for vaccine candidates, including BNT162b2. BNT162b2 is granted a temporary authorization for emergency use (EUA) in the UK, dated 2 December 2020 (Bahrani et al., 2020). This license was Based on a rolling application including data from a global clinical study (NCT04368728) for phase III (Bahrani et al., 2020). This first permit was followed by a quick sequence of BNT162b2 emergency permits or approvals in numerous countries, including Bahrain, Canada, Saudi Arabia, Mexico, and the United States (before 14 December 2020) (Bahrani et al., 2020). Intramuscular (it is better to be in the deltoid muscle) administration of bNT162b2 is suggested for two 30 μg doses with a dosage interval of 21 days. Comprehensive COVID-19 protection must not be established until seven days after the second dosage is given (Polack et al., 2020). In healthy people aged 19–55 years, a strong antibody response was elicited in BNT162b2 by a non-randomized, open-label phase I/II trial (NCT04380701) conducted in Germany (El-Shitany et al., 2021). On 27 June 2021, the Ministry of Health in Saudi Arabia announced that people aged 12 – 18 can take the first dose of the COVID-19 vaccine 'Pfizer.'

While extensive research has been conducted on the side-effects of both the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) and the AstraZeneca COVID-19 vaccine (ChAdOx1 nCoV-19) among the adult population, we believe that it would be beneficial to carry out a similar study among adolescents living in Saudi Arabia considering the recent developments and plans to distribute the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) to adolescents aged 12-18 in the kingdom. Adverse effects of Pfizer-BioNTech COVID-19 vaccine (BNT162b2) among adults: According to a study conducted by (Alhazmi et al., 2021) which had a sample size of 515 individuals, 17% of the 25% of individuals who received the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) reported experiencing adverse effects that range from general tiredness and discomfort at the injection site to fever and chills (Farhud & Zokaei, 2021).

A study by (El-Shitany et al., 2021) in which 455 individuals took part draws a comparison between reported adverse effects after receiving the 1st dose of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) as well after receiving the 2nd dose of the vaccine. However, 122 participants reported adverse effects after the 1st dose and 202 after receiving the 2nd dose, whereas 68 reported adverse effects after receiving both doses of the vaccine. Local symptoms such as discomfort and redness at the injection site, as well as generalizedtiredness, headache, fever, and even rashes, were reported as side effects (Food and Drug Administration (FDA), 2020). The majority mostly experienced local symptoms, including redness, soreness, and swelling at the site of injection. Followed by more systemic symptoms such as generalized tiredness, fever, headache, and muscle pain (Harapan et al., 2020).

The study conducted by Riad et al., (2021) shows that out of the 877 participants who received the Pfizer-BioNTech COVID-19 vaccine (BNT162b2), 93.1% reported experiencing adverse effects, including generalized fatigue, headache, and muscle aches, all of which were not as common as local symptoms at the injection site which accounted for 89.8% of reported adverse effect. Frenck et al., (2021) conducted a study in which 2260 adolescents received injections where 1131 received Pfizer-BioNTech COVID-19 vaccine (BNT162b2) while the remaining participants were given a placebo. Adverse effects were reported in both groups, although they

were less reported among the placebo group. Adverse effects range from local symptoms at the site of injection to fever, tiredness, lymphadenopathy, and appendicitis (Khan et al., 2021).

As vaccination of the adolescent population has just been recently approved in the kingdom of Saudi Arabia, our team has recognized the need to conduct a study on the adverse effects resulting from the Pfizer-BioNTech COVID-19 vaccine by collecting and analyzing data through an online survey to interpret said data and spread awareness on the safety of the vaccine among the public. The objective of this study was to identify the symptoms of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) on adolescents aged 12-18 years living in Saudi Arabia.

2. METHODOLOGY

Study design

Our study was a cross-sectional, online survey that was conducted in Saudi Arabia over one month from August to September 2021. In the middle of 2021, Pfizer- BioNTech vaccine was launched to vaccinate the 12–18-year-old population against COVID-19 in Saudi Arabia. An online questionnaire was developed using Google Forms that are accessible via social media to participants. In order to communicate among researchers and participants, an email was also created. Investigators applied strict measures to ensure confidentiality and viability of responses. The survey was divided into two main parts. The first part provided general information about participants like gender, age, chronic conditions, and the status of COVID-19. The second part focused on the vaccine-related COVID-19 data, such as commonly related side-effects, the time and duration of the side effects, and finally, if there is any need for hospitalization after receiving the vaccine.

Subjects

The study included all adolescents aged 12-18 who are vaccinated, whether a first or two doses in the Kingdom of Saudi Arabia, and included both genders.

Inclusion criteria

Inclusion criteria were as follows: (1) Adolescents aged between 12 years and 18 years. (2) Adolescents who live in Saudi Arabia. (3) Adolescents who receive eitherthe first or the two doses of the vaccine.

Exclusion criteria

Exclusion criteria included all individuals younger than 12 or older than 18, unvaccinated individuals, or those who received a vaccine dose other than the Pfizer-BioNTech COVID-19 vaccine are excluded. Individuals living outside Saudi Arabia are excluded.

Sample size

The sample size 384 was found to be sufficient to provide a 95% interval of confidence for a population of 5 million, with a 5 percent error margin.

Data collection

The main method for data collection was an online questionnaire drawn up on google forms. The questionnaire consisted of four sections. The first section asked the participant's legal guardian for their consent, while the second section inquired about the participant's age, gender, nationality, city, and province. The third section inquired about chronic disease status, known allergy status, current medications, and COVID-19 status. The fourth section inquired about adverse effects experienced by the participants, medications used to manage said adverse effects, and whether the participants have been hospitalized or not due to said adverse

Statistical analysis

The statistical package for the social sciences (SPSS, version 27.0) was used for data analysis. Age was not normally distributed and was summarized by the median and interquartile range (IQR). Frequency tables with correlated percentages were used for categorical variables. The symptoms associated with the COVID-19 vaccine were treated as outcome variables. A Chi-square test was done to find significance with the demography and medical history of the participants. P-values less than (0.05) were considered significant.

3. RESULTS

A total of (1,599) response was analyzed. The minimum age was 12 years, with the median age being 16 (IQR=15-18). Of the total, 45.3% were males. See the related sociodemographic characteristics in (Table 1). The majority (87.3%) did not have chronic diseases, 4.8% had asthma, 2% had obesity, 1.6% had diabetes, 0.8% had arthritis, 1.2% had other chronic conditions, and 2.3% had more than one disease. Regarding allergy, 77.9% indicated that they do not have any known allergy, 7.8% dust allergy, 3.4% food allergy, 2% pet allergy, 1% drug allergy, 1.4% had other allergies, and 6.5% had different types of allergies. The majority (73.4%) were vaccinated with two doses, while the rest had only one dose. Prior to vaccination, 18.7% were diagnosed with COVID-19.

Table 1 The sociodemographic characteristics of the participants

Variable	Number	Percentage (%)
Sex		
Male	724	45.3%
Female	875	54.7%
Nationality		
Saudi	1556	97.3%
Non-Saudi	43	2.7%
Level of education		
Elementary school	28	1.8%
Middle school	443	27.7%
High school	916	57.3%
College	212	13.3%
Province		
Makkah	415	26%
Aseer	425	26.6%
Riyadh	183	11.4%
Madinah	84	5.3%
Jizan	61	3.8%
Najran	10	0.6%
Hail	13	0.8%
Al-Qasim	20	1.3%
Tabuk	207	12.9%
Al-Baha	65	4.1%
Al-Jawf	8	0.5%
Eastern	100	6.3%
Northern	8	0.5%

The participants were asked to choose the symptoms associated with the vaccine doses and to indicate which dose (first, second, or both) was associated with each symptom. The results are shown in detail in (Table 2 and Figure 1). Each symptom was later mentioned to the participants to indicate the duration (one day, two days, three days, more than three days). The details are shown in (Table 3).

The symptoms were tested for significant associations with the demography, chronic diseases, allergy, and previous diagnosis of COVID-19. Some demography variables, in addition to chronic diseases and allergies, revealed invalid P-values due to the fact that they had more than 20% of the expected cell counts having values less than five. However, sex and previous diagnosis of COVID-19 revealed valid association results, as shown in Table 4.

Table 2 The symptoms associated with the doses of the COVID-19 vaccine.

Symptoms	**First dose**		**Second dose**		**Third dose**	
	N	%	N	%	N	%
Pain at the site of injection	461	39.9%	118	10.3%	752	65.1%
Swelling at the site of injection	202	17.5%	141	12.3%	155	13.4%

Redness at the site of injection	163	14.1%	116	10.1%	96	8.3%
Warmth at the site of injection	159	13.8%	130	11.4%	168	14.5%
Itch	131	11.4%	94	8.2%	111	9.6%
Fever	188	16.3%	305	26.6%	192	16.6%
Chills	106	9.2%	200	17.5%	75	6.5%
Muscle pain	214	18.5%	232	20.3%	277	24.0%
Joint pain	111	9.6%	152	13.3%	153	13.2%
Headache	219	19.0%	256	22.4%	235	20.3%
Dizziness	123	10.7%	180	15.7%	101	8.7%
Anxiety	70	6.1%	70	6.1%	42	3.6%
Nausea	74	6.4%	134	11.7%	61	5.3%
Abdominal pain	63	5.5%	87	7.6%	37	3.2%
Vomiting	32	2.8%	47	4.1%	14	1.2%
Diarrhea	39	3.4%	53	4.6%	27	2.3%
Fatigue	96	8.3%	171	14.9%	80	6.9%
Palpitation	42	3.6%	68	5.9%	24	2.1%
Paralysis	14	1.2%	8	0.7%	4	0.3%
Paresthesia	47	4.1%	34	3.0%	29	2.5%
Nasal obstruction	52	4.5%	52	4.5%	26	2.2%
Foreign body sensation at the throat	38	3.3%	53	4.6%	20	1.7%
Throat swelling and tightness	27	2.3%	37	3.2%	14	1.2%
Difficulty breathing	39	3.4%	64	5.6%	26	2.2%
Wheezing	27	2.3%	20	1.7%	11	1.0%
Cough	60	5.2%	66	5.8%	18	1.6%
Hoarseness	34	2.9%	49	4.3%	16	1.4%
Odynophagia	39	3.4%	49	4.3%	11	1.0%
Chest discomfort	50	4.3%	70	6.1%	25	2.2%
Skin rash	16	1.4%	22	1.9%	7	0.6%
None	72	6.2%	19	1.7%	67	5.8%

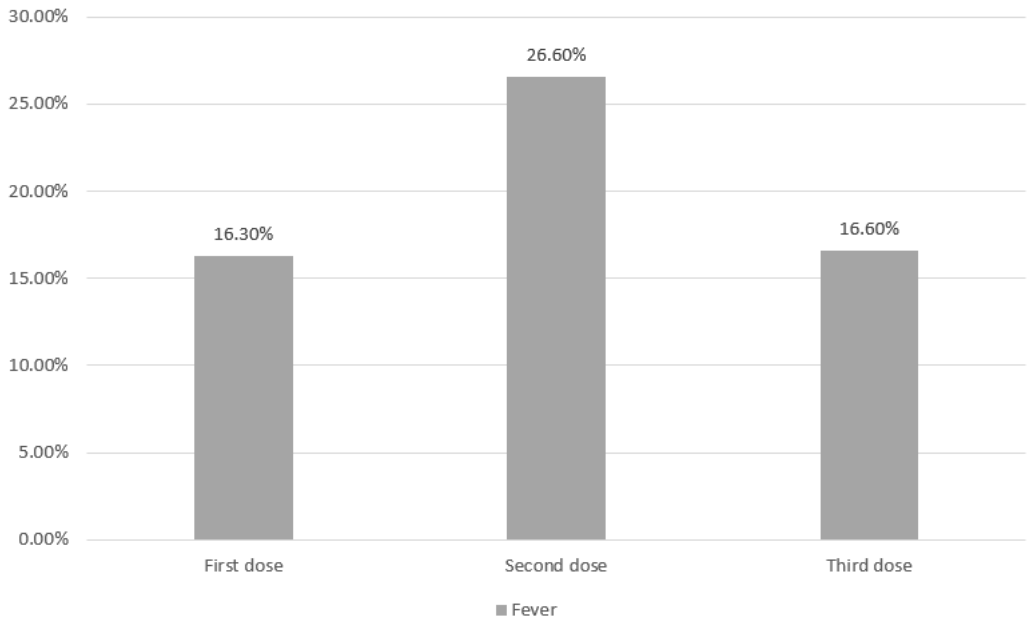

Figure 1 The Fever symptom frequency associated with the doses of the COVID-19 vaccine.

Table 3 The duration of symptoms associated with the COVID-19 vaccine.

Symptoms	One day		Two days		Three days		More than 3	
	N	%	N	%	N	%	N	%
Pain at the site of injection	242	21.0%	437	38.2%	403	34.9%	233	59.6%
Swelling at the site of injection	104	9.0%	163	14.2%	142	12.3%	92	23.5%
Redness at the site of injection	103	8.9%	124	10.8%	94	8.1%	65	16.6%
Warmth at the site of injection	147	12.7%	142	12.4%	87	7.5%	37	9.5%
Itch	68	5.9%	102	8.9%	69	6.0%	58	14.8%
Fever	244	21.1%	228	19.9%	133	11.5%	39	10.0%
Chills	120	10.4%	121	10.6%	70	6.1%	25	6.4%
Muscle pain	128	11.1%	210	18.3%	145	12.5%	95	24.3%
Joint pain	80	6.9%	121	10.6%	93	8.0%	69	17.6%
Headache	198	17.2%	194	16.9%	130	11.2%	86	22.0%
Dizziness	121	10.5%	95	8.3%	63	5.4%	45	11.5%
Anxiety	57	4.9%	40	3.5%	22	1.9%	30	7.7%
Nausea	79	6.8%	68	5.9%	43	3.7%	24	6.1%
Abdominal pain	56	4.9%	56	4.9%	35	3.0%	18	4.6%
Vomiting	40	3.5%	33	2.9%	18	1.6%	10	2.6%
Diarrhea	25	2.2%	42	3.7%	29	2.5%	20	5.1%
Fatigue	62	5.4%	95	8.3%	72	6.2%	41	10.5%
Palpitation	35	3.0%	40	3.5%	27	2.3%	18	4.6%
Paralysis	15	1.3%	15	1.3%	7	0.6%	4	1.0%
Paresthesia	43	3.7%	34	3.0%	19	1.6%	10	2.6%
Nasal obstruction	25	2.2%	32	2.8%	31	2.7%	28	7.2%
FB* sensation at the throat	26	2.3%	33	2.9%	26	2.2%	20	5.1%
Throat swelling and tightness	21	1.8%	26	2.3%	16	1.4%	15	3.8%
Difficulty breathing	38	3.3%	30	2.6%	22	1.9%	22	5.6%
Wheezing	20	1.7%	13	1.1%	18	1.6%	13	3.3%
Cough	38	3.3%	33	2.9%	29	2.5%	33	8.4%
Hoarseness	24	2.1%	24	2.1%	23	2.0%	20	5.1%
Odynophagia	22	1.9%	23	2.0%	19	1.6%	18	4.6%
Chest discomfort	35	3.0%	36	3.1%	32	2.8%	24	6.1%
Skin rash	12	1.0%	15	1.3%	12	1.0%	13	3.3%

*FB: Foreign Body

Table 4 The association of symptoms with the participants' demography

Symptoms	Chi-square P-value	
	Sex	Confirmed COVID-19
Pain at the site of injection	0.001*	0.002*
Swelling at the site of injection	0.005*	0.087
Redness at the site of injection	0.044*	0.007*
Warmth at the site of injection	0.209	0.013*
Itch	0.041*	0.014*
Fever	0.056	0.000*
Chills	0.003*	<0.001*
Muscle pain	0.044*	<0.001*
Joint pain	0.999	<0.001*
Headache	0.023*	<0.001*

Dizziness	0.005*	0.001*
Anxiety	0.264	0.008*
Nausea	0.047*	0.031*
Abdominal pain	0.217	0.004*
Vomiting	0.770	0.011*
Diarrhea	0.866	0.001*
Fatigue	0.253	0.000*
Palpitation	0.034*	0.014*
Paralysis	0.136b	0.239b
Paresthesia	0.056	0.269
Nasal obstruction	0.308	0.007*
FB* sensation at the throat	0.055	0.156
Throat swelling and tightness	0.031*	0.241
Difficulty breathing	0.002*	0.008*
Wheezing	0.060	0.048*
Cough	0.015*	0.048*
Hoarseness	0.077	0.057
Odynophagia	0.440	0.514
Chest discomfort	0.001*	0.014*
Skin rash	0.355b	0.116b

*The Chi-square statistic is significant at the .05 level.

b. More than 20% of cells in this sub-table have expected cell counts less than 5.

Chi-square results may be invalid.

4. DISCUSSION

The findings from this research prove the occurrence of negative effects from the Pfizer-BioNTech vaccine among Saudi Arabian adolescents aged 12-18 years. Vaccines have played a significant role in preventing the spread of infectious diseases during pandemics throughout healthcare history (Magadmi & Kamel, 2021). Scientists believe that vaccination remains an effective intervention in controlling COVID-19 disease due to the lack of a proven treatment approach (Magadmi & Kamel, 2021). However, concerns regarding the potential risks and adverse effects of vaccines have always been on the rise (Magadmi & Kamel, 2021). Recent studies have observed different side effects among different populations. Moreover, the acceptance rate of COVID-19 vaccines varies across different parts of the world (El-Elimat et al., 2021). This study aimed to contribute to world research regarding the adverse effects of the Pfizer-BioNTech vaccine in Saudi Arabian children aged between 12-18 years. The side effects experienced by different people were determined by the type of vaccine administered.

The most common symptoms identified in previous researches include headaches, fever, tiredness, flu-like symptoms, and pain at the injection site (Alghamdi et al., 2021). Similar symptoms were also observed in our research among adolescents. According to an article, the less common side effects among study participants were breathing difficulties, drowsiness, fast heart rate, swelling of lymph nodes, chill, whole body aches, and chills (Alghamdi et al., 2021). Moreover, these symptoms were noticeable within 24 hours after receiving the vaccination (Mohammed et al., 2021). However, the same study reported continuity of symptoms, especially among individuals experiencing pain at the site of injection, fatigue, and muscle pain (Mohammed et al., 2021).

This study's main results identified that most children experience negative side effects during vaccine administration, which subsides over time. A majority of the adolescents experienced pain, warmth, tiredness, redness, chills, and swelling at the site of injection (Mohammed et al., 2021). Similarly, other reports and studies regarding the effects of the COVID-19 vaccine report that the negative effects experienced only last for a few days among a majority of the children (Hause et al., 2021). A strong immune system could account for the disappearance of side effects among children compared to older adults after a few days (Alhazmi et al., 2021). According to this study's research results, the second dose's side effects were higher than those during the first dose (Alhazmi et al., 2021). These results are similar to other research conducted by Alamir et al. regarding the side effects of the Pfizer-BioNTech vaccine (Alhazmi et al., 2021).

Previous studies identified a higher prevalence of negative side effects among females compared to males (Cuschieri et al., 2021). Similarly, our research reported that female participants had more side effects compared to their male counterparts. Gender

differences could account for the difference in the vaccine's immunogenicity (Cuschieri et al., 2021). Furthermore, there was a significant association between the side effects experienced and the number of doses received by individuals in other studies as well (Alghamdi et al., 2021; Cuschieri et al., 2021). Additionally, individuals with a history of the COVID-19 disease experienced different side effects from individuals who had not been exposed to the SARS-CoV-2 virus (Alghamdi et al., 2021). Research results reveal that individuals who had previously contracted the disease manifest more negative side effects than those with no previous history of the disease (Alghamdi et al., 2021).

According to previous investigations, improved immunity results in the production of inflammatory cytokines (Eller et al., 2008). The cytokines have an inflammatory effect that may cause swelling in the muscles, vascular system, and other body tissues (Eller et al., 2008). The immune response among adolescents was non-inferior compared to that of young adults. Most side effects also occur after a few days of the second dose vaccine administration. As shown by the findings from a previous study, several people experienced adverse side effects in the research after getting the second vaccine dosage (Eller et al., 2008). Most people also experience severe allergic effects after the administration of the Pfizer-BioNTech COVID-19 vaccine (Harapan et al., 2020). Acute allergic reactions might develop for those allergic to the vaccine within a few minutes to an hour after the vaccine administration (Harapan et al., 2020). Such allergic reactions were all possible symptoms of an acute allergic reaction. The immunogenicity and efficacy observed among adolescents in other studies establish that Pfizer vaccine will prevent asymptomatic infections among children and improve community protection against COVID-19 (Eller et al., 2008).

The safety of vaccines is constantly evaluated to identify any adverse reactions they may cause. The results of this research, just like the majority of the reported adverse effects of COVID-19 vaccinations, are less severe and last for only a few days. Discomfort at the vaccination site, fever, fatigue, headache, muscular pain, and diarrhea are all prevalent adverse effects of this medication (Hause et al., 2021). The likelihood that these effects may develop following immunization diverges depending on which vaccine is administered. Since the beginning of vaccine manufacture, individuals have raised concerns about their administration's potential dangers and risks. Individuals' level of confidence in vaccines varies widely (Khan et al., 2021). It is inclined on several factors by varying aspects, including their level of knowledge about vaccines, perceptions of potential risks, personal experiences, spiritual affiliation, or political affiliation (Khan et al., 2021). Furthermore, it has been deduced that the method individuals evaluate vaccination-associated hazards compared to other risks differs from how specialists do. Some adverse effects in clinical trials are improbable because of the low frequency with which they occur, the limited number of participants, and other research limits (Khan et al., 2021).

As a result, it is critical to conduct post-marketing surveillance of these adverse effects after vaccination delivery. Following the completion of this investigation, the information gathered from participants indicated that the most detrimental effects of the vaccination were recorded after the second dose. Headaches, flu-like symptoms, fever, and exhaustion are among the most prevalent side effects of injection site discomfort and headaches. Tachycardia, fatigue, trouble breathing, joint distress, chills, and sleepiness are among the less common adverse effects of the vaccine (Eller et al., 2008). Chest discomfort, obstruction of the nasal cavity, odynophagia, and other rare adverse effects have also have been reported. It was shown that people were more likely to have these symptoms after the second vaccination, although discomfort at the injection site was more prevalent among those over 16 years of age. These findings agreed with the "FDA Fact Sheet for Recipients and Caregivers" (Abdul & Mursheda, 2020). On the other hand, regarding the information on the fact sheet, "the most common adverse reactions, which include pain at the point of injection, fatigue and headaches, muscle and joint ache and chills, as well as elevated body temperature, could last for several days and were more severe after the subsequent shot. In light of the immune system's reaction, this discovery might be interpreted in many ways.

A study has revealed that inflammatory cytokines produced by the immune system may cause swelling in the vascular system, muscles, and other body tissues (Riad et al., 2021). This might also be why most side effects manifest after a few days and after the second dose. The investigation indicated that the Pfizer-BioNTech COVID-19 vaccination might have the potential to cause a severe allergic response in certain people (22.1%) (Riad et al., 2021). Following the administration of the vaccination dosage, an acute allergic reaction might develop within a few minutes to an hour for those allergic to the vaccine (Riad et al., 2021). Such allergic reactions were all possible symptoms of an acute allergic reaction. As shown by the findings, several people experienced adverse side effects in the research after getting the second vaccine dosage (Riad et al., 2021).

The study found that after the second dosage, the proportion of those experiencing adverse side-effects rose dramatically. This study's findings contrasted what was found by (Polack et al., 2020) who found that injection site discomfort patients who reported experiencing detrimental signs after two dosages of the vaccination were substantially identical to those after the first dose of the vaccine (Shakoor et al., 2021). However, the outcomes of both this trial and their investigations were similar in terms of swelling

and soreness at the injection site (Shakoor et al., 2021). Other studies also found that systemic adverse effects linked with vaccines were more prevalent among younger persons and after the subsequent vaccination dose.

Strengths

This research made useful contributions to identifying the Pfizer-BioNTech vaccine's adverse effects among children between 12-18 years. Therefore, this study becomes among the first studies that comprehensively describe the negative side effects of COVID-19 vaccines. Furthermore, this research significantly contributes to the increased acceptance rates of COVID-19 vaccines globally. The study results reveal that most people experience short-lived side effects during administration and a few days after vaccination.

Limitations

Our study only focused on the short-term negative side effects of the Pfizer-BioNTech vaccine. The study should have included a broader scope to cover medium-term and long-term symptoms of the Pfizer-BioNTech vaccine. Additionally, the study participants included in the research were small. It would have been more effective and accurate to include a larger sample that represents the entire population. Another limitation is that the study only included adolescents aged 12-18 years and participants from Saudi Arabia. Including participants across all age groups and races would have been more practical because they would have been a true representation of the world's population.

5. CONCLUSION AND RECOMMENDATIONS

This study identified the most common negative side-effects of the Pfizer-BioNTech vaccine among children aged 12-18 years in Saudi Arabia. The research concluded that the most common side-effects experienced lasted only for a few days among a majority of the study participants. The common negative side-effects included pain, headache, dizziness, redness, itchiness, swelling, and diarrhea. Furthermore, these effects were experienced more during the second dose of the vaccine as compared to the first dose. Only a small percentage of the children were hospitalized due to the side effects of the Pfizer-BioNTech vaccine. The data revealed from this study is useful to help increase the confidentiality and acceptance rate among the public to receive the Pfizer-BioNTech COVID-19 vaccine. Most of the side effects of the Pfizer-BioNTech vaccine are widely accepted as common vaccination effects. The results from this study reveal a correct observation of the population due to the consistency with other related researches. Moreover, the side-effects recorded in this study were in line with Pfizer's fact sheet.

This study recommends the evaluation of medium and long-term side effects of the Pfizer-BioNTech vaccine since we only focused on the short-term negative effects. Additionally, we recommend the inclusion of a larger population during further studies for more practical and accurate research results that represents the entire population. In conclusion, our study recommends a follow-up on patients with negative side effects to determine the severity of the symptoms and hospitalization rate.

Acknowledgment

We would like to thank all the participants in this study for cooperating in the research by taking part actively and investing their time

Ethical consideration

Ethical approval was obtained from Research Ethics Committee at International Medical Center with the IRB approval number (2021-08-175).

Funding

This study has not received any external funding.

Conflict of interest

The authors declare that there are no conflicts of interest.

Data and materials availability

All data associated with this study are present in the paper.

REFERENCES AND NOTES

1. Abdul K, Mursheda K. Munich Personal RePEc Archive Knowledge, Attitude and Acceptance of a COVID-19 Vaccine : A Global Cross-Sectional Study. Munich Pers RePEc Arch 2020; (105236).
2. Al BahraniS, Albarrak A, AlghamdiO, Alghamdi M, Hakami F, Al Abaadi A, Alkhrashi S, Alghamdi M, Almershad M, Alenazi M, El Gezery M, Jebakumar A, Al-Tawfiq J. Safety and Reactogenicity of the ChAdOx1 (AZD1222) COVID-19 Vaccine in Saudi Arabia. Int J Infect Dis 2021; 110:359-362.
3. Alghamdi A, Ibrahim A, Almutairi R, Joseph M, Alghamdi G, Alhamza A. A cross-sectional survey of side effects after COVID-19 vaccination in Saudi Arabia: male versus female outcomes. J Adv Pharm Educ Res 2021; 11(2):51–6.
4. Alghamdi AN, Alotaibi MI, Alqahtani AS, Al Aboud D, Abdel-Moneim AS. BNT162b2 and ChAdOx1 SARS-CoV-2 Post-vaccination Side-Effects among Saudi Vaccinees. Front Med 2021; 8(October):1–10.
5. Alhazmi A, Alamer E, Daws D, Hakami M, Darraj M, Abdelwahab S, Maghfuri A, Algaissi A. Evaluation of Side Effects Associated with COVID-19 Vaccines in Saudi Arabia. Vaccines 2021; 9(6):674.
6. Almaghaslah D, Alsayari A, Kandasamy G, Vasudevan R. COVID-19 vaccine hesitancy among young adults in Saudi Arabia: A cross-sectional web-based study. Vaccines 2021; 9(4):1–8
7. Cuschieri S, Borg M, Agius S, Souness J, Brincat A, Grech V. Adverse reactions to Pfizer-BioNTech vaccination of healthcare workers at Malta's state hospital. Int J Clin Pract 2021; 75(10):1–6.
8. El-Elimat T, AbuAlSamen MM, Almomani BA, Al-Sawalha NA, Alali FQ. Acceptance and attitudes toward COVID-19 vaccines: A cross-sectional study from Jordan. PLoS One 2021; 16(4 April):1–15.
9. Eller T, Vasar V, Shlik J, Maron E. Pro-inflammatory cytokines and treatment response to escitaloprsam in major depressive disorder. Prog Neuro-Psychopharmacology Biol Psychiatry 2008; 32(2):445–50.
10. Elsaid S, Ahmed A, Hassan S. Fracture Resistance and Retention of CAD/CAM Endo-Crowns Using Different Preparation Designs. Al-Azhar Dent J Girls 2020; 7(2):203–11.
11. El-Shitany NA, Harakeh S, Badr-Eldin SM, Bagher AM, Eid B, Almukadi H, Alghamdi BS, Alahmadi AA, Hassan NA, Sindi N, Alghamdi SA, Almohaimeed HM, Mohammedsaleh ZM, Al-Shaikh TM, Almuhayawi MS, Ali SS, El-Hamamsy M.Minor to moderate side effects of pfizer-biontech COVID-19 vaccine among saudi residents: A retrospective cross-sectional study. Int J Gen Med 2021; 14:1389–401.
12. Farhud DD, Zokaei S. A Brief Overview of COVID-19 Vaccines. Iran. J Public Health 2021; 50(7).
13. Food and Drug Administration (FDA). Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum. 2020; 2019:47.
14. Harapan H, Wagner AL, Yufika A, Winardi W, Anwar S, Gan AK, Setiawan AM, Rajamoorthy Y, Sofyan H, Mudatsir M. Acceptance of a COVID-19 Vaccine in Southeast Asia: A Cross-Sectional Study in Indonesia. Front Public Heal 2020; 1–8.
15. Hause AM, Gee J, Baggs J, Abara WE, Marquez P, Thompson D. COVID-19 Vaccine Safety in Adolescents Aged 12 – 17 Years. Morb Mortal Wkly Rep 2021; 70(31):5.
16. Immunogenicity of Pfizer-BioNTech COVID-19 vaccine in patients with inborn errors of immunity. J Allergy Clin Immunol 2021; 148(3):739–49.
17. Khan A, AlsofayanY, Alahmari A, Alowais J, Algwizani A, Alserehi H. COVID-19 in Saudi Arabia: the national health response. East Mediterr Health J 2021; 8(3):1–8.
18. Magadmi RM, Kamel FO. Beliefs and barriers associated with COVID-19 vaccination among the general population in Saudi Arabia. BMC Public Health 2021; 21(1).
19. Mohammed RA, Garout RM, Wahid S, Ayub F, Firas ZinAlddin LM, Sultan I. A Survey on the Side Effects of Pfizer/BioNTech COVID-19 Vaccine among Vaccinated Adults in Saudi Arabia. Cureus 2021; 13(11).
20. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med 2020; 383(27):2603-2615.
21. Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 Vaccine Side Effects among Healthcare Workers in the Czech Republic. J Clin Med 2021; 10(7):1428.
22. Shakoor MT, Birkenbach MP, Lynch M. ANCA-Associated Vasculitis Following Pfizer-BioNTech COVID-19 Vaccine. Am J Kidney Dis 2021; 78(4):611–3.